

around three areas—regulatory roles, resource allocation, and organizational structure—and teams have been formed within each area to achieve the following objectives.

Regulatory Roles

The overall objective is to determine the regulatory roles that should be used in a HACCP environment to hold industry accountable for meeting its food safety and other consumer protection responsibilities.

- Determine the best regulatory approaches, tools, and techniques that could be used to ensure food safety in establishments operating HACCP systems.
- Determine the best regulatory approaches, tools, and techniques that could be used to ensure that products are properly labeled, not misbranded, and not economically adulterated both in establishments and between the establishments and the marketplace.
- Determine strategies to ensure that food safety programs are functioning at points in the farm-to-table continuum other than at the in-plant level.
- Determine what knowledge, skills, abilities, and training are necessary to carry out FSIS roles at the different points along the farm-to-table continuum.
- Determine strategies and techniques to better define the distinct roles and responsibilities of FSIS and industry in ensuring food safety.

Resource Allocation

In light of the Agency's goal to reduce foodborne illness, the overall objective is to determine the optimal allocation of Agency resources.

- Determine the optimal allocation of resources between health and safety activities and economic adulteration, labeling, and misbranding activities.
- Determine how to build flexibility into the resource allocation system.
- Determine what support activities are best performed in the field or at headquarters.
- Determine what level of laboratory activities is necessary for regulatory oversight of industry operations and what testing responsibilities should be best undertaken by the industry and by FSIS.

Organizational Structure

The overall objective is to determine the optimal structure needed for headquarters and the field to carry out the goals and strategies of the pathogen reduction/HACCP regulation and to administer the program of the future.

—Examine options for administrative streamlining in line with the goals set by the Administration and the reinvention objectives outlined in the National Performance Review.

- Determine from what location (field, headquarters, or other central location) various FSIS program and administrative support activities are most likely to be effectively and efficiently carried out.
- Determine how policy and regulation development activities can be better managed within the Agency.
- Determine the nature of supervisory and managerial responsibilities and examine better methods for delivering technical information.

The Top-to-Bottom Review Project

The top-to-bottom review project is designed to determine what changes must be completed within 2 to 4 years to implement the proposed regulation for pathogen reduction and HACCP systems.

Communication will be an integral part of the review process. Information will be provided regularly to employees and constituent groups to let them know what activities are ongoing, why these activities are being carried out, how employees and the various groups will be affected, and how they can become involved in the process. The Agency will ensure that the broadest possible input is received from employees and constituent organizations.

A review group composed of several teams has been assigned to each question above. The teams expect to identify the major issues and potential options related to changes in roles, resources, and structure by late summer. At that time, FSIS plans to solicit feedback from its internal and external constituencies on those issues. The Agency will consider these comments as it decides what changes to make to align itself with its public health, food safety, and consumer protection goals. FSIS expects to make decisions on many of these changes by the end of the calendar year, when the Agency expects to finalize the proposed rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems."

FSIS welcomes any comments on the initiatives announced in this notice (See **FOR FURTHER INFORMATION CONTACT**).

Done at Washington, DC on: June 14, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1270

[Docket No. 93N-0453]

Screening and Testing of Donors of Human Tissue Intended for Transplantation; Draft Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Screening and Testing of Donors of Human Tissue Intended for Transplantation." This draft document is intended to provide additional opportunity for individuals to submit comments on screening and testing of donors of human tissue for transplantation. The availability of the draft document is to coincide with the workshop on Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives to be held June 20 and 21, 1995, in Bethesda, MD. The workshop was announced in the **Federal Register** of May 24, 1995.

DATES: Written comments on the draft document should be submitted by July 20, 1995.

ADDRESSES: Single copies of the draft document will be made available to those attending the workshop. Persons not attending the workshop who would like to receive a copy of the draft document should submit a written request for single copies to the Congressional and Consumer Affairs Branch (HFM-12), Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852-1448. Send two self-addressed adhesive labels to assist that office in processing your requests.

Persons with access to the INTERNET may request the draft document be sent by return E-mail by sending a message to "TISSUE1@A1.CBER.FDA.GOV". The draft document may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, "CDV2.CBER.FDA.GOV". The "READ.ME" file in that subdirectory describes the available documents,

which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the READ.ME file with a test based FTP program would be:

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FTP CDV2.CBER.FDA.GOV
LOGIN ANONYMOUS
<ANY PASSWORD>
BINARY
CD CBER
GET READ.ME
EXIT
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The draft document may also be obtained by calling the CBER FAX Information System (FAX-ON-DEMAND) at 301-594-1939 from a FAX machine with a touch tone phone attached or built-in.

Submit written comments on the draft document to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The draft document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Martha A. Wells, Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0967.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 24, 1995 (60 FR 27406), FDA published a notice announcing a public workshop on Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives to be held on June 20 and 21, 1995, from 8:30 a.m. to 5:30 p.m., at the National Institutes of Health, Bldg. 45, Natcher Auditorium, 9000 Rockville Pike, Bethesda, MD. The purpose of the workshop is to provide an opportunity for continued discussion of FDA's interim rule on human tissue for transplantation published in the **Federal Register** of December 14, 1993 (58 FR 65514). The workshop will include discussions of other related issues, including possible regulation of reproductive tissue. The notice stated that one of the objectives of the public workshop is to provide an opportunity for discussion of current screening and testing practices for donors of human tissue for transplantation and human reproductive tissue.

The draft document, developed by a task force composed of FDA staff from CBER, is designed to focus discussion towards specific points on testing and screening donors of human tissue intended for transplantation. The document includes the following topics: Required donor testing, donor suitability and screening test performance, plasma dilution, testing algorithm, sources of information for donor screening, behavioral risk information, clinical evidence of human immunodeficiency virus and hepatitis, and suitable autopsy.

Copies of the draft document will be available at the workshop. A copy of the draft document will be placed on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. To accommodate interested persons who do not attend the workshop, as well as those who will be attending the workshop, FDA is making the draft document available for public comment and will consider such comments in any future rulemaking and in the development of regulatory policies. Comments should be submitted to the Dockets Management Branch (address above) by July 20, 1995.

FDA does not intend this draft document to be all-inclusive. This document does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any private person, but is intended merely for discussion.

Dated: June 14, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Chapter II

Semiannual Regulatory Agenda; Correction

AGENCY: Minerals Management Service, Interior.

ACTION: Correction to semiannual regulatory agenda.

SUMMARY: The Minerals Management Service's (MMS) semiannual regulatory agenda (also known as Unified Agenda) was published on May 8, 1995 (60 FR 23462). This document corrects some information appearing in the May 8 agenda.

FOR FURTHER INFORMATION CONTACT:

Bettine Montgomery, Policy and Management Improvement, at (202) 308-3976, FAX (202) 208-4891.

SUPPLEMENTARY INFORMATION: The corrections to the agenda are as follows:

Proposed Rule Stage

1766. Payor Responsibilities, RIN: 1010-AB45

On page 23462, in the second column, the CFR citation listed for this rule was incorrect. The correct CFR citation is 30 CFR part 211. The information in the timetable section of the agenda for the proposed rule is also incorrect. The correct information is the proposed rule published on June 9, 1995 (60 FR 30492).

Completed/Longterm Actions

1781. Valuation of Oil and Gas From Indian Leases, RIN: 1010-AB57

On page 23466, in the first column, the agenda incorrectly listed this rule as withdrawn. The rule has neither been completed nor withdrawn. The correct information is that an Advance Notice of Proposed Rulemaking was published on August 4, 1994 (59 FR 39712). The comment period closed October 3, 1994. On February 7, 1995, the Secretary of the Interior established an Indian Gas Valuation Negotiated Rulemaking Committee to reach consensus on certain issues. A proposed rule will be drafted based on the agreement reached by the committee. The publication date for the proposed rule is currently undetermined.

1783. Limitations on Credit Adjustment Submitted by Lessees and Other Royalty Payors Under Federal and Indian Mineral Leases, RIN: 1010-AB73

On page 23466, in the second column, the agenda incorrectly listed this rule as withdrawn. This rule has neither been completed nor withdrawn. The rule will be combined with RIN 1010-AB74 and published as one rule under RIN 1010-AB73. The Notice of Proposed Rulemaking was published August 17, 1993 (58 FR 43588). The comment period closed November 1, 1993. The next action will be to publish the final combined rule; this is scheduled to be published in March 1996 or earlier.

1784. Collection of Royalties, Interest, and Other Amounts Due Under Federal and Indian Mineral Leases by Administrative Offset, RIN: 1010-AB74

On page 23466, in the third column, the Agenda incorrectly listed this rule as withdrawn. This rule has neither been completed nor withdrawn. Instead,